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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/393,795 | 09/10/1999 | JOHN T. GRAY | CMCC693P2A | 3301 |

21005 7590 04/09/2002

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EXAMINER

LEFFERS JR, GERALD G

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1636

DATE MAILED: 04/09/2002

20

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/393,795

Applicant(s)

GRAY ET AL.

Examiner

Gerald Leffers

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 January 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-49 is/are pending in the application.
- 4a) Of the above claim(s) 4,6,11,15,19,21,26,30,34 and 38-49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5,7-10,12-14,16-18,20,22-25,27-29,31-33,35-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/22/02 has been entered.

Receipt is acknowledged of applicants' amendment, filed 1/22/02 as Paper No. 19, in which claims were amended (claims 1, 5, 7-8, 12, 16, 20, 22-23, 27, 31 and 35). Claims 1-49 are pending in the instant application, with claims 4, 6, 11, 15, 19, 21, 26, 30, 34, 38-49 are withdrawn from consideration as being directed towards nonelected inventions. Any rejection of record in the previous office action (Paper No. 15) not addressed in this office action has been withdrawn.

It is noted that in Paper No. 19 the claims were amended to specify that the packaging vector of the invention does not comprise a Rev Response Element (RRE). This does not affect the following rejection for lack of enablement for embodiments wherein the packaging vector does not comprise an RRE. As no new issues have been raised by the amendment to the claims in Paper No. 19, this action is FINAL.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

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pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 5, 7-10, 12-14, 16-18, 20, 22-25, 27-29, 31-33, 35-37 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for packaging cell lines (as well as methods of constructing/using such cell lines or the particles produced from such methods) featuring a first lentiviral nucleotide sequence which comprises codon optimized coding sequences for gagpol operatively linked to a Rev Response Element (RRE) and which does not also comprise coding sequences for the viral accessory proteins or a constitutive transport element (CTE), does not reasonably provide enablement for embodiments wherein the first lentiviral nucleotide sequence does not comprise the gagpol sequences operatively linked to a RRE. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the claimed invention commensurate in scope with these claims. **This rejection is maintained for reasons of record in Paper No. 15, mailed 12/15/00.**

Response to Arguments

Applicant's arguments filed in Paper No. 19 have been fully considered but they are not persuasive. The response essentially argues: 1) the specification need not have an example if the specification is otherwise disclosed in a manner as to be enabling, 2) Kim et al do not question the use of applicants' three plasmid system, and 3) Kim et al does not provide evidence that would lead one skilled in the art to the conclusion that applicants' claimed invention is unbelievable.

The examiner at no time indicated that applicants' claimed invention must be reduced to practice in order for the invention to be enabled. As part of a full Wands analysis of the prior art

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and instant specification, it was noted that a working example wherein the packaging vector lacks any CTE or RRE sequence would have indicated that practicing the claimed invention would be predictable. The assertions that the teachings of Kim et al are not applicable to applicants' system and do not call into question whether applicants' system would function as claimed are inaccurate. The major difference between the system claimed by applicants and that described is that the gagpol sequence found on applicants' packaging vector has been codon-optimized for expression. Codon-optimization would not be expected to have any bearing on efficient transport of the nucleic acid comprising the optimized gagpol sequences. The response has presented no evidence or rational to indicate why the findings taught by Kim et al do not apply to the claimed packaging system. Given that the teachings of Kim et al do apply to the claimed system, that the teachings of Kim et al do call into question the predictability of practicing the claimed invention, and given the lack of sufficient guidance in the instant specification or prior art as to how to make the claimed invention work predictably in the absence of a RRE or CTE element on the packaging vector comprising the gagpol sequence, it would take undue, unpredictable experimentation to practice the claimed invention.

Conclusion

No claims are allowed.

This is a continuing examination of Applicants' earlier Application No. 09/393,795. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a

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first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G Leffers Jr. whose telephone number is (703) 308-6232. The examiner can normally be reached on 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-7939 for regular communications and (703) 305-7939 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Gerald G Leffers Jr.
Examiner
Art Unit 1636

ggl
April 8, 2002

DAVID GUZO
PRIMARY EXAMINER
